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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,677	04/19/2007	Robert Gordon Hood	9931-010US	4798

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EXAMINER	
TANNER, JOCELIN C	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
06/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

international@dblaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,677	HOOD ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,17-23,25 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 17-23, 25, 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/15/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed 15 March 2010. Claims 1-3, 17-23, 25, and 28-30 are currently pending. The Examiner acknowledges the amendments to claims 1, 2, 17-19, 21, 22 and 28-30 and the cancellation of claims 4-16, 24, 26, 27, 31 and 32.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 21, the recitation "the intravascular stent insert is a stent graft" is unclear since the specification of the instant application states that the intravascular stent includes an stent insert and the intravascular stent can be a stent-graft [0067] but fails to describe the stent insert as a stent-graft. For the purposes of art rejection, the Examiner will interpret the claim to require the stent to be a stent-graft.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 17-23, 25, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (US PGPub No. 2003/0139807) in view of

Falotico et al (US Patent No. 7,195,640) in view of Greenhalgh (US Patent No. 6,159,239).

6. Regarding claim **1**, Houston et al. discloses a wire mesh intravascular stent having a blood-contacting surface on its interior, a polyurethane stent insert [0039] having a helical formation on the blood contacting surface (FIG. 1, element #2), the helical formation including at least one fin (FIGs. 3-6), the helical formation being capable of inducing helical flow of blood flowing past [0042]. However, Houston et al. fails to disclose a drug releasably associated with the helical formation and the formation having a helix angle between 8° and 20°.

Falotico et al. teaches a coated medical device that may be coated with any number of therapeutic drugs, agents or compounds (column 10, lines 3-5, column 12, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the helical stent of Houston et al. with the therapeutic and pharmaceutical drug coating, as taught by Falotico et al., for the prevention of multiple components of neointimal hyperplasia or restenosis and to reduce inflammation and thrombosis (column 11, lines 10-15).

Greenhalgh teaches a helical stent (72) having a helix angle between 10° and 85° which encompasses the claimed range of 8° and 20°(column 13, lines 57-67, column 14, lines 1-10, Fig. 12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of the combination of Houston

et al. and Falotico et al. with a helical angle between 8° and 20°, as taught by Greenhalgh, to obtain substantially homogeneous compressive and flexural properties for the stent (column 14, lines 1-5).

7. Regarding claim **2**, the combination of Houston and Falotico discloses all of the limitations previously discussed. Further, Falotico et al. teaches a stent or "drug delivery device" formed by the mixing of a polymer and rapamycin, an antibiotic used to treat restenosis, by directly incorporating rapamycin into a polymeric matrix wherein the rapamycin elutes from the polymeric matrix over time into the surrounding tissue (column 14, lines 1-4 and column 18, lines 50-59).

8. Regarding claim **3**, Falotico et al. teaches coating the inner and outer surface of the stent with drug/drug combinations wherein the inner surface contains the helical formation (column 12, lines 53-55).

9. Regarding claim **17**, Houston et al. discloses a helical formation made from polymer foam [0050].

10. Regarding claim **18**, Houston et al. discloses a helical formation made from polyurethane [0039].

11. Regarding claim **19**, Falotico et al. teaches a drug that is bound onto the cellular structure of the polymer through crosslinking wherein the pharmaceutical agents are bonded to the atoms and chains of the polymers of the coatings and films (column 19, lines 65-67).

12. Regarding claim **20**, Falotico et al. teaches therapeutic and pharmaceutical coatings of antiplatelet agents, anticoagulants and fibrinolytic agents (column 10, lines

14, 29-30 and column 18, lines 29-30) wherein the coatings can be layered to control release of different agents placed in different layers (column 18, lines 2-4).

13. Regarding claim **21**, Houston et al. discloses a vascular implant that is a stent, stent graft and a graft [0011] having an insert therein.

14. Regarding claim **22**, Houston et al. discloses a membrane or "sleeve" positioned within the stent that is made of flexible material and attached to the body of the stent [0046].

15. Regarding claim **23**, Houston et al. discloses the sleeve being formed of PTFE material [0046].

16. Regarding claim **25**, the combination of Houston et al. and Falotico et al. discloses a drug that is releasably associated with the blood-contacting surface of the stent and helical formation attached thereto wherein an inner surface coating (column 12, lines 53-55) containing therapeutic agents are applied into and onto the stent by way of spraying, spinning or dipping (column 14, lines 29-31) and the drug is released through diffusion dependent on the desired release profile (column 19, lines 29-36).

17. Regarding claim **27**, Houston et al. discloses a helical formation having at least one fin (FIG. 3, element #6 and #7, [0048]).

18. Regarding claim **28**, Houston et al. discloses a fin having the shape of a right-angle triangle in cross-section (FIG. 5, [0048]).

19. Regarding claim **29**, Houston et al. discloses a fin having the shape of an isosceles triangle in cross-section (FIG. 6, [0049]).

20. Regarding claim **30**, Houston et al. discloses a fin having the shape of a bell in cross-section (FIG. 7).

Response to Arguments

21. Applicant's arguments filed 15 March 2010 have been fully considered but they are not persuasive. The Applicant contends that the purpose of the helical insert of Houston et al. is different than that of the helical stent member of Greenhalgh such that a skilled person would not have produced such a combination. However, the insert of Houston et al. is adapted to be attached to an internal side wall of the stent [0011] to generate spiral flow and though the stent member of Greenhalgh is woven to the exterior of the stent, other locations (e.g. interior surface) are within the scope of the invention of Greenhalgh (column 14, lines 1-16). The Greenhalgh reference was used to teach that an insert having a helix angle between 8° and 20° is well known and capable of giving a stent-graft substantially homogenous compressive and flexural properties. The rejection citing Brown et al. have been withdrawn since Brown et al. fails to disclose a wire mesh intravascular stent.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
6/02/2010
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/5/10